

South Africa Reverses Course On AIDS Drugs

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Cape Town -- IN A DRAMATIC shift in its AIDS policy, the South African government said it will undertake the world's largest AIDS treatment program by providing the expensive and complex AIDS drug regimens free of charge.

The decision ends years of divisive debate that delayed treatment for AIDS patients and mired South African President Thabo Mbeki in controversy. South Africa has more HIV-infected people than any other country in the world -- 5.3 million, according to the latest health department estimate, out of a total population of about 45 million. The decision by the nation's cabinet commits the country to one of the most ambitious public-health programs ever attempted in sub-Saharan Africa, and the endeavor will challenge the country's struggling health system. But if it succeeds, it could become a model for AIDS treatment in Africa.

In announcing the cabinet's decision, Health Minister Manto Tshabalala-Msimang said that without "a fall in the prices of drugs over the past two years" the program "would have been impossible." Indeed, the treatment plan follows, and will likely take advantage of, a deal announced last month by the Clinton Foundation HIV/AIDS Initiative and four generic-drug companies, including one in South Africa. That deal slashed the price of AIDS medicine by more than a third from already discounted prices, and is available to South Africa and several other African and Caribbean nations that former President Bill Clinton is assisting. In addition, almost 25 advisers from the Clinton Foundation helped the South African government develop the plan.

Peter Piot, director of the Joint United Nations Program on HIV/AIDS, or UNAIDS, said the South African program "has the potential to be the world's foremost treatment initiative in the world." He added that "I particularly want to acknowledge President Mbeki's personal commitment to this program. This has been a long journey for him, but today he can rightly be proud."

More than four years ago, Mr. Mbeki began questioning mainstream science about the causes and treatment of the disease. The president's aides insisted he was acting responsibly by raising critical questions and focusing on social factors such as poverty, but many doctors and activists reacted with outrage at what they saw as dithering and denying while hundreds of thousands died.

The more than 600-page AIDS treatment plan that the cabinet approved calls for antiretroviral AIDS drugs to be available within the first year of the program in all 53 health districts in the country, even those in the most remote and impoverished areas. As of the end of June, only about 76,000 patients in the whole of sub-Saharan Africa were taking antiretroviral treatment, according to Axios International, a consulting firm that collates sales data from six large pharmaceutical companies. Under the program adopted yesterday, within five years more than a million South Africans are expected to embark on the lifelong regimens. For the estimated 25% of patients who can't afford proper meals, the government will hand out nutrition packs containing vitamin and mineral supplements, as well as a daily meal.

To make such a program feasible -- and to make sure it doesn't drain resources from other health-care efforts -- the government has committed to large investments in recruiting and training doctors and nurses, and in improving laboratory services and drug distribution. Indeed, the drugs themselves add up to only about a third of the program's budget. "Implementation of this plan will benefit the health system as a whole," said Ms. Tshabalala-Msimang.

The cost of the program starts at 296 million rand, or \$45 million, for the rest of this fiscal year and is estimated to rise to approximately 4.5 billion rand a year, or about \$680 million, by fiscal year 2007-08. That's about 11.5% of South Africa's current public-sector health spending, according to Finance Minister Trevor Manuel.

The plan recommends that South Africa should pay for "the biggest slice" of the program out of its own treasury rather than with donor funding. South Africans don't want to depend on other nations partly because they want to ensure funding is in place for patients to take antiretroviral drugs uninterrupted for life, as is needed to prevent onset of the disease. And like many developing nations, South Africa is skeptical of aid promises. Donor money for AIDS treatment might fall off because of "a war or postwar reconstruction efforts required here or there," Mr. Manuel said.

The treatment program poses huge challenges. The biggest is the brute fact that although the government has built 700 clinics since the fall of apartheid almost a decade ago, the country's health system remains overburdened, in part because AIDS patients are flooding the wards. Even major urban hospitals report frequent shortages of medicines and other essentials. The public-health system is short about 30,000 nurses. The AIDS program won't eliminate that shortfall but plans to bring in more than 5,000 new nursing staff.

Meanwhile, huge numbers of South Africans go to traditional healers for herbal remedies. Could those preparations, some of which have strong effects on the body, interfere with AIDS drugs? Or will gastrointestinal diseases, which are rampant in poor areas, prevent the drugs from being absorbed properly? Also, a large proportion of South African AIDS patients comes down with active TB. Should doctors treat TB first and then HIV, or both?

To answer such questions, the plan calls for a major research effort, complete with a database of patients enrolled in AIDS care. South Africa's huge HIV-positive population, most of whom have never taken AIDS drugs, offers researchers "a unique opportunity to answer outstanding questions on how best to use the drugs -- and that will benefit the whole world," said Eric Goosby, chief executive officer of the San Francisco-based Pangea Global AIDS Foundation. Dr. Goosby worked on the plan as part of the Clinton Foundation HIV/AIDS Initiative.

While expensive, the treatment program is budgeted at much less than what the South African government estimated it would cost in August. A major reason is the new Clinton Foundation drug deal.

However, South Africa has the continent's strictest patent laws, so it is unclear how quickly the government can take advantage of the Clinton deal, which so far involves only generic-drug makers. Some of those companies, such as Indian drug makers Ranbaxy Laboratories Ltd. and Cipla Ltd., lack licenses from the patent holders to produce the medicines. Therefore, say some legal experts, South Africa might have to issue compulsory licenses or negotiate with patent holders to persuade them to issue such licenses voluntarily.

In the meantime, South Africa can use the Clinton Foundation prices -- as low as 38 cents a day for one triple-drug regimen -- as a negotiating tool. Still, it might have to purchase the drugs from the patent holders at substantially higher costs, which could bring negative publicity upon the big pharmaceutical companies.

The South African generics maker involved in the Clinton deal, Aspen Pharmacare Holdings Ltd., does have licenses to produce almost all of the AIDS drugs South Africa plans to use. But only one of its AIDS drugs has been approved for use by the South African government.

Terrible Toll

South Africa's HIV/AIDS epidemic at the end of 2001.

-- Population: 43.8 million

-- AIDS deaths: 360,000

-- Adults and children living with HIV/AIDS: 5 million

-- Children orphaned by AIDS: 660,000

Source: UNAIDS

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